Ethics and Governance of Health Research Data in International Organizations: A Framework Analysis

Qing Cheng
School of Health Policy and Management, Chinese Academy of Medical Sciences & Peking Union Medical College, Beijing 100730, China
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Abstract: Taking the relevant policies of health research data issued by international organizations as the research object, using the life cycle theory, this paper constructs an international ethics governance framework for health research data from the perspectives of governance stages and means. It summarizes the connotation, means, and policy focus of international organizations' ethics governance for health research data. This paper aims to provide references for countries worldwide to optimize the ethics governance of health-related research data, improve the governance level of health research data, and foster a robust ecosystem for data opening and sharing.
***Keywords*:** health research data; data sharing; scientific data governance; ethics; protection of privacy

1. Introduction

Health research data is a nationally strategic basic resource and a core production factor in promoting the innovation of medical science and technology. In recent years, with the continuous development of the open science movement and the emergence of new data-driven scientific research paradigms, governance and open sharing of health research data have become important tasks in the international medical field[1]. The international definition and connotation of health research data are similar, encompassing not only data generated during scientific research in the medical field but also data from clinical diagnosis and treatment, health examinations, disease monitoring, and other medical practices used or shared for medical scientific research. The sources of health research data are complex and diverse, including personal attribute data, health data, genetic and biometric data, and other sensitive personal privacy data. The ethical governance issues surrounding data are more complex and prominent in this field than in others[2]. Therefore, based on health research data ethics, it is urgent to explore how to effectively promote the open sharing of health research data.

2. Research methods

2.1 Policy Screening Process

This paper took the health research data governance policies issued by international organizations as the research objects, including guidelines, principles, declarations, statements, and other international agreements and related policies. We used "biomedical research data," "health research data," "health database,'" and "health data" as search terms to systematically search the official websites of institutions related to health research data, such as the World Health Organization (WHO), the United Nations Educational, Scientific, and Cultural Organization (UNESCO), the United Nations Human Rights Office of the High Commissioner (OHCHR), the Organisation for Economic Cooperation and Development (OECD), the Council for International Organizations of Medical Sciences (CIOMS), the World Medical Association (WMA), The Human Genome Organization (HUGO), the International Science Council (ISC), and the Research Data Alliance (RDA). We then manually screened the relevant policy documents for content related to medical science data governance. In addition, in the medical field, a biobank is a collection of biological materials and related data, which is the core of medical research, and its biological information data is an important data source for medical scientific research[3]. Therefore, this paper searched for relevant governance policies of biobanks and extracted the sections related to data ethical governance for inclusion. After a final review, 25 policy documents were selected and arranged in chronological order, as shown in Table 1 below.

Table 1. International Organizations' Policies for Ethical Governance of Health Research Data

Number	Policy title	Policy-issuing authority	Year of policy issuance
1	The Declaration of Helsinki (DoH)[4]	WMA	1964
2	The Bermuda Triangle: The Pragmatics, Policies, and Principles for Data Sharing in the History of the Human Genome Project[5]electronic health records, and "omics" technologies have produced a deluge of data. Making meaning of those data—creating scientific knowledge and useful clinical information—will vastly exceed the capacity of even the largest institutions. Data must be shared to achieve the promises of genomic science and precision medicine.","container-title":"Genome Research","DOI":"10.1101/gr.216911.116","ISSN":"1088-9051","issue":"6","journalAbbreviation":"Genome Res","note":"PMID: 28373484\nPMCID: PMC5453323","page":"897-901","source":"PubMed Central","title":"Moving beyond Bermuda: sharing data to build a medical information commons","title-short":"Moving beyond Bermuda","volume":"27","author":[{"family":"Cook-Deegan","given":"Robert"},{"family":"McGuire","given":"Amy L."}],"issued":{"date-parts":[["2017",6]]}}}],"schema":"https://github.com/citation-style-language/schema/raw/master/csl-citation.json"}	HGP	1996
3	Universal Declaration on the Human Genome and Human Rights[6]	UNESCO	1997
4	Statement on Human Genomic Databases[7]	HUGO	1998
5	Declaration on Ethical Considerations Regarding Health databases[8]	WMA	2002
6	International Ethical Guidelines for Biomedical Research Involving Human Subjects[9]	CIOMS, WHO	2002
7	Sharing Data from Large-scale Biological Research Projects: A System of Tripartite Responsibility[10]	International conference	2003
8	International Declaration on Human Genetic Data[11]	UNESCO	2004
9	Universal Declaration on Bioethics and Human Rights[12]	UNESCO	2005
10	Principles and Guidelines for Access to Research Data from Public Funding[13]	OECD	2007
11	International Ethical Guidelines for Epidemiological Studies[14]	CIOMS, WHO	2008
12	Recommendations from the 2008 International Summit on Proteomics Data Release and Sharing Policy: The Amsterdam Principles[15]	International conference	2008
13	Guidelines for Human Biobanks and Genetic Research Databases (HBGRDs) [16]	OECD	2009
14	Best practices for repositories: Collection, storage, retrieval, and distribution of biological materials for research[17]	ISBER	2012
15	Guidelines on the Protection of Privacy andTransborder Flows of Personal Data[18]	OECD	2013
16	Declaration of Taipei on Ethical Considerations regarding Health Databases and Biobanks[3]	WMA	2016
17	Report of the IBC on big data and health [19]	UNESCO	2017
18	Recommendation on The Protection And Use of Health-Related Data[20]	OHCHR	2019
19	COVID-19 Recommendations and Guidelines on Data Sharing[21]	RDA	2020
20	World Health Organization Data Principles[21]	WHO	2020
21	Recommendation-of-the-Council-on-Enhancing-Access-to-and-Sharing-of-Data[22]	OECD	2021
22	Health Research Performing Organisations (HRPOs) FAIR Guidelines[23]	RDA	2022
23	Sharing and Reuse of Health-Related Data for Research Purposes: WHO Policy and Implementation Guidance[24]	WHO	2022
24	Health Data Governance for the Digital Age[25]	OECD	2016
25	WHO Personal Data Protection Policy[26]	WHO	2024

2.2 The international policy research framework for ethics governance of health research data

International organizations such as WMA, CIOMS, WHO, and OECD have issued many policies to continuously promote ethical governance and open sharing of health research data, which have played an important role in promoting the open sharing of data in the medical field. International health research data governance activities are rooted in existing laws, regulations, and ethical principles, and legitimacy is an important compliance of governance activities. Therefore, data ethical governance is an important part of data governance. Data ethics governance is mainly conducted around the data value cycle/data life cycle. The different stages of governance are divided into five phases: collection, processing, storage, sharing and use, and disposal. In terms of governance means, it refers to the data governance framework recommendations put forward in the OECD Principles and Guidelines for Access to Research Data from Public Funding and Health Data Governance for the Digital Age, and classifies governance practices from four aspects: legal and administrative, technical, cultural and behavioral to form an ethical governance framework[13,25]. The specific meanings of each dimension are shown in Table 2. The particular governance content according to each classification dimension is summarized in Table 3

Table 2. International health research data ethics governance policy framework

Governance Dimensions		Connotation
Governance stages	Collection	The process of collecting data from data subjects
	Processing	All relevant processing procedures involving personal health data, including preprocessing, cleaning, deduplication, formatting, conversion, and de-identification.
	Storage	The process of storing data of different life cycle stages in appropriate storage devices/storage databases based on different data types and data characteristics, and implementing reasonable data management.
	Sharing and use	The process of presenting scientific data in a way that allows research institutions, researchers, and the public to access and use it fairly. This includes the data sharing process of data producers/managers and the usage process of data users.
	Disposal	The final disposal stage of scientific data. This includes the process of preserving and managing the original data set and data products, as well as the process of handling and deleting the data when it is no longer needed.
Governance means	Law and Administration	International agreements, national laws, policies, and regulations that directly impact data openness and sharing. This includes legal protections for data rights such as intellectual property and privacy, government budgetary support and administrative regulations related to institutional management.
	Technology	Promoting technical infrastructure for the acquisition and utilization of scientific data: such as technical measures related to data interoperability, data quality control, and data security protection.
	Culture and Behavior	This refers to the practice of educating and rewarding the subjects that fund, produce, manage and use scientific data to promote data acquisition and sharing.

Table 3. International Health Research Data Ethics Governance Content

Governance stages Governance means	Law and Administration	Technology	Culture and Behavior
Collection	Data Management Plan (DMP);	Data Classification and Grading;	Ensure transparency and information disclosure;
	Principle of informed consent;		Public and Patient Involvement (PPI);
	The principle of purpose limitation;		Data investment;
	The principle of minimizing personal data;		Data Reward Mechanism
	Data Protection and Privacy Officer;		
Processing	Data Management Plan (DMP);	Data Encryption Technology;	Fair and Legal Handling;
	Data Processing Agreement;	Data Pseudonymization;	Artificial Intelligence and Transparent Regulations for Medical Algorithms;
	Special Protection Principles for Sensitive Personal Data;	Data Anonymization;	Public and Patient Involvement (PPI);
	Special Protection Principles for Genetic Data;	Privacy Enhancing Technologies;	Data Reward Mechanism;
	Data Risk Assessment;	Statistical Disclosure Control;	
	Data Protection and Privacy Officer	Secure Enclave;	
		Differential Privacy Tools;	
		Key Indexing Technology;	
		Statistical techniques such as the removal of direct identifiers, aggregated values, and categorical variables;	
		Distributed Remote Computing	
Storage	Data Management Plan (DMP);	Data storage time limit;	Public and Patient Involvement (PPI);
	Data Availability Statement;	Data Classification and Grading;	Data Reward Mechanism
	Data Risk Assessment;	Guidelines for Data Storage;	
	Data Protection and Privacy Officer	Data backup;	
		Sensitive Data Storage Management Framework	
sharing and use	Data Management Plan (DMP);	Statistical Disclosure Control;	Public and Patient Involvement (PPI);
	Data Protection and Privacy Officer;	Re-identification risk assessment;	Data Reward Mechanism;
	Data Access/Use protocol;	Access control mechanisms;	Contract/Agreement/License;
	Data transmission protocol;	Usage Restrictions;	Data investment

Governance stages Governance means	Law and Administration	Technology	Culture and Behavior
	Data Protection and Privacy Officer	Hierarchical Access;	
		Identity verification	
	Data Breach Handling Mechanism;		Written agreement/protocol;
disposal.	Data subject information acquisition, access, rectification, deletion, and restriction of processing;		Public and Patient Involvement (PPI);
	Data update;		Law Enforcement Remediation Mechanisms
	Data Transfer Protocol		

3. Results

3.1 The stage of data collection

The common problems in the practice of data ethics governance in this stage include illegal data collection and creation, an insufficient guarantee of individual participants/patients' right to privacy and informed consent.To this end, international organizations have established systematic data protection regimes and established a Data protection authority such as the Data Security and Monitoring Commission (DSMC) or the Data Access Committee (DAC) to evaluate and review the data, Coordinate multi-stakeholder relations to ensure that individual participant/patient privacy and other rights are fully protected. Secondly, the International organizations has established a special Data Protection and Privacy Officer (DPPO), which acts as the first contact for the personal data protection of individual participants/patients, protects the rights and interests of data subjects, and provides information about their relevant rights and interests to data subjects.To handle requests from data subjects and to take action in the event of a breach of personal data, the Commissioner has an independent function, reporting directly to the Director General to ensure the independence of their work.In the specific practice of ethics governance at the collection stage, principles such as the purpose limitation, personal data minimization, risk minimization, and data confidentiality are primarily adhered to. That is, international organizations stipulate that data collection should be relevant to the research purpose, and only the minimum amount of data required to complete the purpose should be collected. Furthermore, data should be obtained by legal and fair means, with the clear and specific informed consent of the data subject. Data of different types and sensitivity levels are classified to ensure data security and confidentiality. Data should be collected in ways that are less risky and less burdensome for individual participants or populations.

In addition, international organizations have established a multi-level scientific data governance structure to promote the full cooperation and participation of all stakeholders, including patients, researchers, users, and citizens at large. Internationally established mechanisms for Public and Patient Involvement (PPI) enable the public and patients to participate in the entire data life cycle, from the initiation of research questions to the implementation of data collection and the final data sharing and use, thereby fully protecting the rights and interests of patients and the public. Furthermore, training and capacity building for data collection personnel are provided, and reward and recognition mechanisms are established to ensure that project personnel who collect and generate data sets receive sufficient support, thus promoting the formation of a responsible scientific data governance culture and ecology.

3.2 The stage of data processing

The common problems in the practice of data ethics governance at this stage include incomplete privacy and data security technologies, as well as imperfect data security mechanisms. To address these issues, international organizations have established strict data processing systems, developed a series of technologies for data security and privacy protection, regulated personal data processing activities, and protected the basic rights of individuals by effectively allocating responsibilities and obligations to stakeholders. First, international organizations specify that health-related data must be processed consistently with the purposes for which it was originally collected. Second, data must be assessed by an independent competent authority, including lay members, before processing, such as an ethics committee or the Data Protection and Privacy Commissioner (DPPO). The evaluation includes scientific research objectives, ethical principles, expected processing outputs, data processing limitations, and risks faced by data subjects or groups. In addition, international organizations have established special protection principles for sensitive personal data and genetic data. Sensitive personal data and genetic data can only be processed when necessary, and only after the Data Protection and Privacy Commissioner

(DPPO) has been informed and granted approval. When processed, they are separated from other types of personal data, stored separately, and access is restricted or controlled. At the technical level, international organizations mostly adopt encryption technology, pseudonymization, anonymization, privacy enhancement technology, statistical disclosure control, data security enclaves, differential privacy tools, key index technology, deletion of direct identifiers, and other statistical techniques, and de-identification technology to protect personal privacy.

In addition, international organizations provide training on data processing software and standard operating procedures to enhance the capacity of data processing personnel. They also conduct ethical and legal education and training for researchers, data processing personnel, and the public. These efforts aim to foster a culture of data privacy and security protection and to raise awareness about data privacy.

3.3 The stage of data storage

In the practice of data ethics governance at this stage, common problems include insufficient data protection, inadequate security for storage infrastructure, and a low willingness to openly share data. To address security and privacy issues in the storage process, international organizations have stipulated that health databases and biobanks must be operated by professional personnel and managed through an accountability system to regulate the data storage process. Given the multi-disciplinary and diversified nature of the medical field, a method of data classification and grading management should be established, along with a framework for monitoring and managing data across different disciplines and types. International organizations impose storage time limits on data and establish a sensitive data storage management framework, known as The 5 Safes Model, to provide special protection and secure storage for sensitive data such as genomic data. This is achieved through a comprehensive evaluation of the accessors' qualifications, access purposes, access locations, data content, and research results. Additionally, data is protected by clear security protocols against intentional or unintentional loss, damage, modification, and unauthorized access. Regular reviews and updates of data security measures are conducted to ensure adequate protection relative to the sensitivity and risk exposure of personal information. Furthermore, data backups should be conducted promptly, and infrastructure should be regularly inspected and maintained to protect against environmental hazards such as heat, dust, electrical surges, magnetic fields, and electrostatic discharge.

In addition, international organizations have implemented comprehensive education and training programs for data managers, focusing on technical, legal, and ethical dimensions, and have enhanced communication with stakeholders, including researchers and the public. Furthermore, they have revised existing incentive structures to acknowledge the contributions of data managers to data management activities, considering these efforts a significant factor in promotion evaluations. Concurrently, they have developed storage protocols for professional researchers and scientists to bolster trustworthiness and improve communication efficiency.

3.4 The stage of data sharing and use

Common issues encountered in the practice of data ethics governance at this stage include the leakage of information during data sharing and use, unauthorized use that infringes on the privacy rights and right to know of data subjects; unclear rights of the various parties involved in data sharing, and a low willingness to share data.To address this.international organizations have implemented an accountability management framework for health-related data. In the event of a data leak resulting from its release as open data, both the data handler and the data publisher are held accountable to the data subject. The data subject is entitled to seek effective remedies and compensation. A stringent approval mechanism for data sharing should be established, requiring that all data sharing and usage be authorized and authenticated by users, and that all requests be reviewed by a dedicated Data Access Committee through formalized Data Usage Agreements. If access to confidential information is sought, a confidentiality agreement must be executed to safeguard the data subject's rights. To tackle issues related to unclear rights among stakeholders and the low willingness to share, international organizations advocate for diminishing traditional ownership concepts and promoting a transition from data ownership to shared stakeholder rights. They also support establishing a multi-party responsibility system that emphasizes shared interests, balances principles of equity, and highlights collective rights and responsibilities among data holders, producers, intermediaries, and other relevant stakeholders. Furthermore, it is essential that all parties meticulously document their respective rights and obligations in the Data Management Plan (DMP), ensuring collaborative governance during the phases of open access and shared use.

Additionally, during this phase, international organizations have carried out corresponding education, training, and public awareness campaigns to foster a cultural atmosphere that promotes the open sharing and compliant use of health research data. At the same time, they have made long-term investments in data sharing and use, implementing the Sharing Rewards and Credit (SHARD) mechanism to ensure that stakeholders' data sharing and use behaviors, in accordance with legal and ethical frameworks, are supported, encouraged, recognized, and rewarded.

3.5 The stage of data disposal

One of the common problems in the practice of data ethics governance at this stage is improper data disposal, violating privacy rights, the right to informed consent, and data subjects' rights to access, modify, delete, and transfer their data. Therefore, international organizations have clearly stated that if data is identifiable, its disposal still requires the data subject's informed consent and respects the rights of individual participants to withdraw consent. Data subjects have the right to withdraw consent. Specific policies have been formulated to protect vulnerable groups, such as minors, individuals with impaired decision-making ability, and the elderly. Given that genomic data is highly identifiable, international organizations have stipulated that identifiable genetic data must be destroyed once the research purpose has been fulfilled, and genetic test data must not be repurposed for other research.

Furthermore, international organizations promote good practices in ethical governance during the data disposal stage, aiming to enhance the level of international medical scientific data governance. They also intensify the implementation of knowledge dissemination and promotion plans that address legal and ethical issues, aiming to raise public awareness about the protection of their rights and foster a culture of responsible and sustainable data sharing.

4. Conclusion

Based on the relevant policies, guidelines, and other documents governing health research data from international organizations, this paper summarizes the ethical governance strategies and measures of health research data from the perspective of the data life cycle (collection, processing, storage, sharing, use, disposal). An international ethical governance framework for health research data should be established to provide a reference for national health research data governance. Moving forward, we can focus on five key aspects: data collection, processing, storage, sharing, and use. To Further develop the ethical governance framework for health research data, we should consider data pre-management, establishment of a systematic and standardized data protection system, participation of the public and patients in the data governance process, development of technical tools for data processing and privacy security, formation of data storage norms, establishment of a multi-party responsibility system for data openness and benefit sharing, and encouragement of multi-party cooperation.

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